Translation
of the title page and the passage from line 26 on page 4 to line 36 on page 9 of the French Patent 2 820 630 (Benazzouz Karim)

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DEVICE FOR CONVEYING A BONE SUBSTITUTE SUBSTANCE OR BONE CEMENT TO THE SITE OF A BONE INSTABILITY AND INSTRUMENT FOR OPERATING THIS DEVICE

This device for conveying a bone substitute substance or bone cement to the site of a bone instability is constituted by an implant (1, 40) provided with a bore (8, 41) extending essentially over its entire length and opening flush with the periphery or the end of the implant by through-holes (39, 42); the end of the implant or implants (1, 40), which is opposite to their implantation zone within the bone, is provided with means for connection to an instrument for implantation and for injection of said bone substitute substance.

[Page 4, paragraph 4 to the end of page 9]

In accordance with the invention, the osteosynthesis screw (1), whose two embodiments are better represented with reference to Figures 3a and 3b, is provided with a main external thread (4) permitting its fixation within the bone to be synthesised. This external thread (4) may be self-cutting or not and is envisaged for permitting the fixation of the screw in the porous bone or the cortex.

The upper end (5) of the screw is provided with an element for connection to an instrument for implantation of the screw within the bone and for injection of the bone substitute substance at the site of the fracture centre. In the embodiment represented with reference to Figure 3a, this connecting element is constituted by another external thread (6) having a pitch that may be different or not different from the pitch of the main thread (4). This external thread is intended for interaction with a corresponding thread (30) formed at the site of one of the ends of the implantation and injection instrument, which will be described in details below, so as to ensure its attachment to the latter. It presents moreover a driving element formed at the level of the internal head (7), whose profile is conventionally hexagonal and which is envisaged for interaction with the head (28) of the instrument for fixing the screw within the bone to be synthesised, which presents corresponding dimensions and shapes. This screw comprises a bore (8) extending substantially over the entire length of the screw and is located in parallel with the screw axis or is congruent therewith. Eventually, this bore communicates with the outside by means of a plurality of through-holes (39) formed through the side wall of the screw. It should be set forth here that such through-holes can be created flush with the end of the screw (Figure 4b).

In another embodiment of the invention, which is illustrated in Figure 3b, the connecting element consists of an annular groove (9) whose function is identical with that of the thread (6), i.e. attachment of an instrument for implantation and injection, particularly of bone substitute material, flush with it.

In Figures 2a to 2j, different embodiments of the connecting element are represented which the head of the inventive osteosynthesis screw is provided with. The embodiments in Figures 2b and 2f are discussed as early as here in relation to Figures 3a and 3b.

The connecting element in Figure 2a consists of an internal thread.
The connecting element in Figure 2c consists of a non-opening aperture having a conical shape, which extends the hexagonal receiving part of the screw head.
The connecting element according to Figure 2d consists of a conically shaped peripheral circumference.
The connecting element in Figure 2e is formed by an internal annular groove.
The connecting element in Figure 2g is constituted by an L-shaped groove which may or may not open flush with the side wall of the head.
The connecting element in Figure 2h is formed by two lateral grooves extending substantially orthogonally on the axis of the screw.
The connecting element according to Figure 2i is formed by an internal T-shaped groove starting from the upper end of the screw head.
The connecting element according to Figure 2j is formed by one or several recesses formed in the lateral surface of the screw head.

With respect to the Figures 4a and 4b, two further embodiments of inventive screws are represented, which are envisaged for implantation in the rachis. These screws, for instance of the "tulip" type, are fundamentally analogous to the aforedescribed screws but they present an internal thread (43) at the level of their head (5), which is envisaged for permitting the attachment of a connecting element, particularly a shaft, at this level, which is capable of cooperating with an adjacent shaft that is placed within an adjacent screw. These screws are moreover provided with a fixing element formed at the bottom of the space (7) defined by the head (5), or an internal thread (44) or an annular groove (45), respectively, which are envisaged for cooperation with ancillary means for the injection of a bone substitute substance or cement.

In Figures 6a and 6b, an instrument for the injection of a bone substitute substance into the interior of the screw is represented. This screw is principally configured in the form of a screwdriver provided with a reservoir envisaged to accommodate the material to be injected, i.e. bone substitute substance in this case.

On principle, it comprises, first of all, a main body (25) provided with the reservoir (26) and extending itself by a shaft (27) into which an injection canal is drilled which opens at (28) in correspondence with a standard hexagonal profile, which is adapted to mate the head (7) of the screw (1).

The shaft (27) receives, at its periphery, a gripping element (29) or connector which is provided for permitting the fixed attachment of the end (28) of the ancillary injection means on the screw head, as is also illustrated in more details in the Figures 7a, 7b and 7c or 8a, 8b, 8c. This gripping element or connector may be or may not be blocked in its translational motion.

Hence, the two possible alternatives of translation or non-translation of the gripping element are illustrated in Figures 11a and 11b. According to Figure 11a, the gripping element is not blocked in its translational movement along the shaft (27). The head of the screw does, in fact, not arrive systematically in order to bear against the driving end of the screwdriver. Hence, a play remains between these two elements.

In Figure 11b, the gripping element is provided with one or two radial projections (75) on its inner wall in the vicinity of its end opposite to its site of connection to the screw head, which radial projections are capable of penetrating into one or two grooves (76) of complementary shape which are formed at the periphery of the injection shaft (27), and hence tend to block the translatory movement of said gripping element along this shaft. In doing so it becomes possible to subject the screw, to which the gripping element is connected, to a movement of inverted translation such as the motion indicated by the arrow F which is opposite to the conventional movement for insertion of said screw into the interior of the bone. Hence, a play does not remain between the screw head and the driving end of the screwdriver. In the case of bone substitute substances of very low viscosity the injection can now be performed without the risk of leakage at this site.

In a first case (Figures 7a to 7c), the free end of the gripping element is provided with an internal screw thread (30) which is intended for cooperation with the external screw thread (6) of the screw head.

In another embodiment of the invention (Figures 8a to 8c), the free end of the gripping element (29) is provided with an internal annular projection (31) which is intended for cooperation with the annular groove (9) on the screw represented in Figure 3b.

It should be noted that the free end of the gripping element (29) has a diameter smaller than or equal to the external diameter of the implant head and of the screw in this case, so as to avoid any conflict with a complementary implant such as an osteosynthesis plate, for example.

Expediently a ring (32) made of polyacetal (registered trademark Delrin) is forcefully mounted at the level of the end of the gripping element (29) so as to ensure tightness and equally also the guidance of said gripping element (29) in its rotating movement.

Inside the reservoir (26), a piston (32), whose dimensions are adapted to the reservoir (26) is capable of translatory displacement inside said reservoir and is intended to make it possible that the bone substitute substance inside the reservoir (26) is pressed out first from the canal (27) and then from there in a direction towards the screw or the spindle.

In a first embodiment of the invention, this piston is provided with a bore having an internal screw thread that is intended for cooperation with the external screw thread of an injection shaft (35). The piston (33) is prevented from rotation by means of off-centring its bore relative to the shaft of the reservoir (26), as can be well seen, by the way, in Figure 6b.

This shaft (35) is actuated by means of a knurled knob (36) located at one of its ends. In the embodiment described here, the shaft and hence the threaded rod (35) are off-centred relative to the axis of symmetry of the reservoir (26), thus enabling the piston (33) inside the reservoir (26) to move forward when they are rotated.

The injection shaft (35) is placed inside the main body (25) and is held within the latter by means of a pin (37) in order to secure it against translatory movement, which pin is screwed at the level of a threaded opening (34) situated in the vicinity of the end of the body (25) near the shaft 27 and which, when finally placed, is capable of interacting with an annular groove (24) formed in the vicinity of the end of said shaft (35), thus enabling the shaft to be blocked against translatory movement.

Apart therefrom, the shaft (35) is provided with a groove (23) extending substantially in a linear direction in the vicinity of its free end so as to permit the discharge of the bone substitute substance contained in the reservoir (26) along the direction of the shaft (27).

Eventually, the body (25) accommodates a sleeve (38) made of plastic material, specifically Celeron (registered trade mark) at the level of the periphery of the reservoir (26).

In a configuration illustrated in Figures 15 to 17, the main body (25) of the instrument is capable of being adapted such that it can accommodate a syringe pre-charged with the bone substitute substance (67), together with its operating piston, instead of the reservoir (26). Thus, the syringe (67) slides in the body (25), as can be seen in Figure 15. This syringe may be replaced by a capsule (70) equally pre-charged with the bone substitute substance, or directly by a threaded piston (77') or non-threaded piston (77). The capsule presents also such a shape and particularly such a skirt adapted to the internal volume of the body (25) that it can be inserted into the latter and then be compressed by any known element whatsoever. This capsule may be matched with its receiving element, in particular, in such a manner that it will limit and/or prevent any contact between the instrument and the bone substitute substance. Hence, the latter can flow directly from the capsule to the implant.

The connection of the syringe (67) or the capsule (70) to the extension (27) of the ancillary means is realised either by means of a conical fitting (69), which interacts with the corresponding region (72) located at the end of the body (25) (Cf. Figure 16) or by means of a screw connection, with an external screw thread (73), formed at the level of the end of the syringe (67) or the capsule (70) cooperating with a corresponding internal screw thread (74) formed at the level of the region (72) of the body (25) (Cf. Figure 17) or even by means of an additional threaded element (78) envisaged for ensuring the connection and the tightness between these two elements (Figure 18).

The end of the gripping element (29) has been described with reference to the osteosynthesis screws according to Figures 3a and 3b. It is, of course, apparent that this end is adapted as a function of the connecting element provided on the screw head.

Thus, various possible variants have been schematically represented with reference to Figures 9a to 9k, which are intended, by the way, to be compatible with the screw embodiments described with reference to Figures 2a to 2j.

Figures 9b and 9g have already been briefly discussed the context of the description presented above.

The end of the instrument shown in Figure 9a corresponds to the absence of any connecting element associated with the screw head. With this condition, a certain pressure must be exerted on the instrument in practical application when the latter is placed into the interior of the screw head so as to avoid any risk of leakage of the bone substitute substance during injection.

The end of the instrument presented in Figure 9c corresponds to a connecting element constituted by an internal screw thread (Figure 2a). In this case, it is formed by a screw thread produced on the outside of the gripping element.

The end of the instrument represented in Figure 9d corresponds to a connecting element constituted by an aperture not opening in a conical shape, which does not extend the hexagonal elongated hole of the screw head (Figure 2c). This end is hence formed by an internal fitting presenting a complementary conical shape, which extends the injection shaft (27).

The end of the instrument represented in Figure 9e corresponds to a connecting element constituted by a peripheral circumference having a conical shape (Figure 2d). This end is thus constituted by an external conical fitting of a complementary shape, which extends the gripping element.

The end of the instrument represented in Figure 9f corresponds to a connecting element constituted by an interior annular groove (Figure 2e). The end of the injection shaft (27) hence presents a corresponding resilient annular projection (or a resilient ring), which is formed just downstream of the hexagonal end or inside thereof.

The end of the instrument represented in Figure 9h corresponds to a connecting element constituted by an L-shaped or T-shaped groove beginning from the upper end of the screw head; this L-shaped groove may open or not open at the level of the side wall of said head (Figure 2g). The end of the injection shaft (27) is thus provided with a locking stud projecting relative to its side surface, which is suitable for cooperation with this groove, in this case of a bayonet system.

The end of the instrument represented in Figure 9i corresponds to a connecting element constituted by two lateral grooves extending substantially orthogonally on the axis of the screw (Figure 2h). The end of the gripping element is thus provided with two linear projections oriented towards the inside, which are suitable for cooperation with these two grooves.

The end of the instrument represented in Figure 9j corresponds to a connecting element constituted by an internal T-shaped groove, beginning from the upper end of the screw head (Figure 2i). The end of the injection shaft is thus provided with an external annular projection which is intended for cooperation with this groove.

The end of the instrument represented in Figure 9k corresponds to a connecting element constituted by one or several recesses formed within the lateral surface of the screw head (Figure 2j). The end of the gripping element is thus provided with one or several locking studs which are oriented towards the inside and are suited for cooperation with these recesses.